

Atty Dkt. No.: AERX-088 USSN: 09/990,181

AMENDMENTS

IN THE CLAIMS

Please cancel claim 7 and amend claims 1, 5, 8, 10, 14-19, 21, 27 and 28 as shown below.

1. (Currently Amended) A composition for transfecting a cell with a nucleic acid, comprising:

a <u>DNA</u> sequence chosen from a plasmid, a phagemid and a cosmid nucleic acid; and a cationic aminoglycoside;

wherein said nucleic acid <u>DNA</u> sequence is condensed by interaction with said cationic aminoglycoside.

- 2. (Original) The composition according to claim 1, wherein said cationic aminoglycoside is bacteriostatic, and has an average molecular weight in a range of from 300 Daltons to about 800 Daltons.
- 3. (Original) The composition according to claim 1, further comprising water, wherein the composition has a physiological pH.
- 4. (Original) The composition according to claim 1, wherein said cationic aminoglycoside is selected from the group consisting of Gentamicin, Tobramycin, Amikacin, Streptomycin, Neomycin, Sisomicin and Netilmicin.
- 5. (Currently Amended) The composition according to claim 1, wherein said nucleic acid DNA sequence encodes a biologically active protein amino acid sequence.

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6. (Original) The composition according to claim 1, wherein the composition is aerosolized and comprised of aerosol particles having an aerodynamic diameter in a range of from about 0.5 micrometer to about 12 micrometers.

7. (Canceled)

- 8. (Currently Amended) The composition according to claim 1, wherein said nucleic acid is a high molecular-weight polynucleotide comprising DNA sequence comprises at least one coding region.
- 9. (Original) The composition according to claim 6, wherein the aerosol particles have an aerodynamic diameter in a range of from about 2 micrometers to about 6 micrometers.
- 10. (Currently Amended) The composition according to claim 1, wherein the composition is characterized by an ability to transfect human cells with an efficiency of 200% more as compared to transfer human cells about that obtained in the absence of the cationic aminoglycoside.
- 11. (Original) The composition according to claim 1, wherein said composition is formulated in a pharmaceutical formulation designed to be administered to said cell by a means selected from the group consisting of pulmonary, parenteral, oral, nasal, intraperitoneal, intraocular, intracranial, suppository, dermal, transdermal and buccal.
- 12. (Original) The composition according to claim 1, wherein said composition further comprises at least one functional group, wherein said functional group is selected from the group consisting of targeting moieties, nuclear localization peptides and endosomolytic peptides.

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13. (Original) The composition according to claim 1, wherein said composition further comprises at least one therapeutically acceptable lipid.

- 14. (Currently Amended) The composition according to claim 13, wherein said therapeutically acceptable lipid comprises a liposome encapsulating said <u>DNA sequence</u> nucleic acid.
- 15. (Currently Amended) The composition according to claim 1, wherein said condensation comprises a reduction of about 10³ to about 10⁶ in the physical volume of said <u>DNA sequence</u> nucleic acid.
 - 16. (Currently Amended) A method of transfecting a cell comprising the steps of:
- (a) contacting a composition comprising a nucleic acid DNA sequence chosen from a plasmid, a phagemid and a cosmid, and a cationic aminoglycoside with a cell; and
- (b) allowing said composition to remain in contact with said cell for a period of time and under conditions such that said nucleic acid <u>DNA sequence</u> enters the cell.
- 17. (Currently Amended) The method according to claim 16, wherein said nucleic acid <u>DNA</u> sequence is condensed by the interaction with said cationic aminoglycoside.
- 18. (Currently Amended) The method according to claim 17, wherein said condensation comprises a reduction of about 10³ to about 10⁶ in the physical volume of said <u>DNA sequence</u> nucleic acid.
- 19. (Currently Amended) The method according to claim 16, wherein said <u>DNA sequence</u> nucleic acid encodes a biologically active <u>protein</u> amino acid sequence which is therapeutically effective.

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20. (Original) The method according to claim 19, wherein the contacting is carried out by aerosolizing the formulation and inhaling aerosol into a patient's lungs.

21. (Currently Amended) The method according to claim 20, wherein said the aerosol has particles with an aerodynamic particle size in a range of from about 2 micrometers to about 6 micrometers.

- 22. (Original) The method according to claim 21, wherein said cationic aminoglycoside is selected from the group consisting of Gentamicin, Tobramycin, Amikacin, Streptomycin, Neomycin, Sisomicin and Netilmicin.
- 23. (Original) The method according to claim 22, wherein the composition further comprises at least one therapeutically acceptable lipid.
- 24. (Original) The method according to claim 23, wherein the lipid is a liposome encapsulating said nucleic acid.
- 25. (Original) The method according to claim 16, wherein said contact is accomplished in an environment selected from the group consisting of *in vivo*, *in vitro* and *ex vivo*.
- 26. (Original)The method according to claim 16, wherein the composition is aerosolized prior to contacting and the composition is brought in contact with the cell *via* pulmonary delivery of said composition to a subject.
- 27. (Currently Amended) A method of treatment treating a patient in need of a protein, comprising:

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aerosolizing a formulation comprising a nucleic acid DNA sequence chosen from a plasmid, a phagemid and a cosmid and a cationic aminoglycoside to create aerosol particles having an aerodynamic diameter in a range of from about 0.5 micrometers to about 12 micrometers;

inhaling the aerosol into a patient's lungs; and

allowing the inhaled aerosol to contact cells for a period of time and under conditions such that the <u>nucleic acid DNA sequence</u> transfects the cells and expresses a therapeutically effective amount of a biologically active <u>amino acid sequence protein resulting in treating the patient in need of the protein</u>.

28. (Currently Amended) The method according to claim 27, wherein the aerosoling in is carried out by forcing said composition through pores of a membrane, wherein said aerosol has a particle size ranging from about 2 to about 6 microns.